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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,371	01/25/2005	William Richard Cross	15892.9	1386
22913 7590 03/30/2007 WORKMAN NYDEGGER (F/K/A WORKMAN NYDEGGER & SEELEY) 60 EAST SOUTH TEMPLE 1000 EAGLE GATE TOWER SALT LAKE CITY, UT 84111			EXAMINER SCHUBERG, LAURA J	
			ART UNIT 1657	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	DELIVERY MODE
3 MONTHS			03/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/522,371	Applicant(s) CROSS ET AL.	
	Examiner Laura Schuberg	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 13-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 13-23 are pending and have been examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "the components" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 13, the phrase "like medium" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "like medium"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d). For examination purposes, "like medium" is determined to be any nutrient medium that would be suitable for culturing urothelium.

Because claims 14-23 depend from indefinite claim 13 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13, 15, 17-19, 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al (In Vitro Cell. Dev. Biol.-Animal 2001).

Claim 13 is drawn to a method of production of stratified, differentiated mammalian urothelium in which urothelial cells, isolated from the mammalian body, are passaged through a nutrient medium containing components of serum and redispersed before going on in a like medium to form the urothelium.

Claim 15 includes wherein the serum is bovine serum.

Claims 17-19 include the concentration range of the components of the serum.

Claim 21 includes wherein the nutrient medium is KSFM.

Claim 22 includes wherein the nutrient medium is supplemented by one or more of EGF, BPE, CT.

Claim 23 is drawn to the urothelium produced by the method of claim 13.

Zhang teaches a method for expansion and long-term culture of differentiated normal rat urothelium cells in vitro wherein the urothelium cells are isolated from the mammalian body (page 419 materials and methods) and cultured with a media that contains KSFM and conditioned medium (CM) with 5% fetal bovine serum (FBS) (page 422 table 1). Detailed investigations of culture conditions showed that CM-KSFM yielded a differentiated multilayered (stratified) structure (abstract). Supplementation of the media with EGF, BPE and CT is also taught (page 419 material and methods).

Therefore, Zhang anticipates the invention as claimed.

Claims 13-15, 17, 18, 21, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Liebert et al (Differentiation 1997).

Claim 14 includes wherein the urothelium is human urothelium.

Liebert teaches a method of producing urothelium using isolated human urothelial cells that are cultured with media containing minimal essential medium and 2% fetal and 8% newborn calf (bovine) serum as well as KSFM (page 178 column 1 Methods) and show differentiation (page 184 column 1). Also, cells in low-calcium, serum-free medium (KSFM) maintained at high confluence show evidence of differentiation, especially at higher passages (3-6 passages) (page 184 column 2). Stratification is also achieved as well (abstract line 4). Since the invention as claimed does not require a specific level of differentiation or stratification, any degree of differentiation or stratification found in the prior art urothelium would meet these limitations.

Therefore, Liebert anticipates the invention as claimed.

Claims 13-15, 17, 18, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Scriven et al (The Journal of Urology 1997).

Scriven teaches a method of producing urothelium from cells isolated from urothelium tissue that forms a stratified, polarized transitional-like neo-urothelium that expressed many of the phenotypic and differentiated characteristics of normal tissue (page 1151). The method uses a medium supplemented with 10% fetal bovine serum

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and the cells are passaged and redispersed before going on in a like medium to form urothelium (page 1148 materials and methods). Since the invention as claimed does not require a specific level of differentiation or stratification, any degree of differentiation or stratification found in the prior art urothelium would meet these limitations.

Therefore, Scriven anticipates the invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al (In Vitro Cell. Dev. Biol.-Animal 2001) or Liebert et al (Differentiation 1997) or Scriven et al (The Journal of Urology 1997) in view of Seijiro et al (US 4,654,304).

Claim 16 is drawn to the method of claim 15 wherein the serum is adult bovine serum.

Zhang, Liebert or Scriven teach the method of claim 15 as described above, but do not include adult bovine specifically.

Seijiro teaches that serum to be used in the cultivation of animal cells or tissues may be derived from any species, although bovine, among others, may be advantageously used for reasons of their ready availability (column 1 lines 64-68). The mammals from which the serum is derived may be at any age, e.g., fetuses, newborns, young or adults (column 2 lines 1-2). Clearly adult bovine serum is considered by Seijiro to be a suitable substitute for fetal or newborn bovine serum.

Therefore, one of ordinary skill in the art would have been motivated to substitute adult bovine serum for fetal or newborn bovine serum because Seijiro teaches that mammals from which the serum is derived may be at any age, e.g., fetuses, newborns, young or adults (column 2 lines 1-2). One of ordinary skill in the art would have had a reasonable expectation of success because Seijiro had demonstrated the adult bovine serum possessed growth promoting substances (column 11 table 4).

Therefore, the combined teachings of Seijiro with any one of Zhang, Liebert or Scriven render obvious the invention as claimed.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al (In Vitro Cell. Dev. Biol.-Animal 2001) in view of Judd et al (US 6,692,961 B1).

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Claim 20 includes wherein the nutrient medium is, or is a derivative of, MCDB-153 medium.

Zhang teaches the method of claim 13 using KSFM, but does not teach the use of MCDB-153 medium.

Judd teaches a defined system for epithelial cell culture and indicates that MCDB-153 is a suitable alternative for KSFM medium (column 5 lines 1-13).

Therefore, one of ordinary skill in the art would have been motivated to substitute MCDB-153 medium for KSFM in the method of Zhang because Judd indicates that MCDB-153 is a suitable alternative for KSFM medium (column 5 lines 1-13). One of ordinary skill in the art would have had a reasonable expectation of success because the teachings of Judd were drawn to the in vitro cultivation of animal epithelial cells.

Therefore, the combined teachings of Zhang and Judd render obvious the invention as claimed.

Claims 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liebert et al (Differentiation 1997) in view of Judd et al (US 6,692,961 B1).

Liebert teaches the method of claim 13 as described above, but does not teach the use of MCDB-153 medium or supplementing with EGF, BPE, CT.

Judd teaches a defined system for epithelial cell culture and indicates that MCDB-153 (which includes EGF and BPE) is a suitable alternative for KSFM medium (column 5 lines 1-13). Judd also teaches the benefits of adding EGF and/or cholera toxin (CT) to the media as well (column 11 lines 10-40).

Therefore, one of ordinary skill in the art would have been motivated to use MCDB-153 in the method of Liebert because Judd teaches that MCDB-153 is a suitable alternative for the media that Liebert uses (KSFM). One of ordinary skill in the art would have been motivated to add EGF or CT to the culture media of Liebert because Judd teaches that these agents are beneficial in the growth of epithelial cells. One of ordinary skill in the art would have had a reasonable expectation of success because both Judd and Liebert are growing epithelial cell cultures.

Therefore, the combined teachings of Liebert and Judd render obvious the invention as claimed.

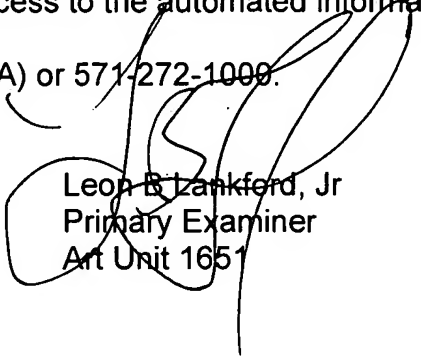
Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Schuberg whose telephone number is 571-272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leon B. Lankford, Jr.
Primary Examiner
Art Unit 1651

Laura Schuberg